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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,590

10/17/2005

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EXAMINER

XIE, XIAOZHEN

ART UNIT

PAPER NUMBER

1646

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,590	<b>Applicant(s)</b> CHO ET AL.	
	<b>Examiner</b> XIAOZHEN XIE	<b>Art Unit</b> 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 06 July 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 May 2005 and 06 July 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>20080722, 20080820</u> .                                      | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

The Information Disclosure Statements (IDS) filed 22 July 2008 and 20 August 2008 have been entered. The replacement drawings submitted on 6 July 2008 have been entered. Applicant's amendments of the specification (specifically, the abstract) and the claims filed on 6 July 2008 have been entered.

Claims 1-4 are pending and under examination.

### ***Oath/Declaration***

A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date has been received on 6 July 2008.

### ***Drawings***

The objection to the drawings (in particular, Figures 1, 3a, 4, 5, 12 and 13) under 37 CFR 1.83(a), as being not legible and fail to show details as described in the specification, is withdrawn in response to Applicant's submission of the replacement drawings.

### ***Specification***

The objection to the abstract for grammatical errors is withdrawn in response to Applicant's amendment of the abstract.

### ***Claim Rejections Withdrawn***

The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, as being lack of enablement, is withdrawn in response to Applicant's amendment to the Sequence Listing to change SEQ ID NO: 1 to a different sequence, i.e., the mature human BMP-7 protein sequence.

***New Grounds of Rejections/Objection***

***Objection to Amendment for New Matter***

The amendment filed 06 July 2008 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: SEQ ID NO: 1.

Applicant is required to cancel the new matter in the reply to this Office Action.

In the remarks of 06 July 2008, Applicant indicates that SEQ ID NO: 1 has been amended to list the sequence of mature BMP-7. Applicant indicates that the sequence of mature BMP-7 was known, and that Applicant had intended to list the sequence of mature BMP-7 rather than the previously listed sequence. Applicant asserts that no new matter has been introduced. This has been fully considered but is not found to be persuasive. The specification as originally filed did not point to the prior art sequence of mature BMP-7, specifically, the new SEQ ID NO: 1, as the appropriate agent useful in the claimed compositions.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

Art Unit: 1646

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 2 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification as originally filed does not provide support for the invention as now claimed: “a mature BMP-7 (Bone Morphogenic Protein-7) polypeptide of SEQ ID NO: 1”. Applicant’s amendment, filed 6 July 2008, asserts that no new matter has been added. However, the instant specification as filed does not provide sufficient written description for the limitation of “a mature BMP-7”. This is a new matter rejection.

Applicant is required to cancel the new matter in the response to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the “limitations” indicated above. See MPEP 714.02 and 2163.06.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Jones et al. (US 5,834,179, issued on 10 November 1998).

The claims are directed to a composition for inhibiting a scar formation comprising an effective amount of a mature BMP-7 (Bone Morphogenic Protein-7) polypeptide of SEQ ID NO: 1 (claim 1); wherein the effective amount of the mature BMP-7 is 50 ng/ml-50 µg/ml or 0.1 ng-1 µg/kg (claim 2); and wherein the scar is a corneal scar (claims 3 and 4).

Jones et al. teach morphogenic protein compositions, e.g., human OP-1 (also known as BMP-7). Jones et al. teach that the morphogenic protein includes the mature form of a morphogen protein subunit; for example, useful mature forms of OP-1 include dimeric species defined by residues 293-431 of SEQ ID NO: 1 (col. 3, lines 29-35). Residues 293-431 of SEQ ID NO: 1 of the '179 patent is identical to the instant SEQ ID NO: 1. Jones et al. teach that the concentration of a morphogenic protein in a therapeutic composition ranges from about 10 ng/kg to about 1 g/kg of body weight per day; or from about 0.1 µg/kg to 100 mg/kg of body weight (col. 24, lines 5-29).

The claim language "for inhibiting a scar formation, wherein the scar is a corneal scar" is an intended use, and is not given patentable weight in this rejection. The only apparent limitation is the protein itself.

Therefore, Jones et al. anticipate the instant claims.

### ***Conclusion***

NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1646

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Xiaozhen Xie, Ph.D.  
October 6, 2008

/Elizabeth C. Kemmerer/  
Primary Examiner, Art Unit 1646